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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/080,504      | 02/22/2002  | Olaf Reinhold        | 38466.00008.UTL     | 8672             |

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EXAMINER

LEWIS, AARON J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3743

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/080,504             | REINHOLD ET AL.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | AARON J. LEWIS         | 3743                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07/20/2005(AMENDMENT).
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-19,21-42,43-61,63-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Voges ('841).

As to claim 1, Voges discloses a device (fig.2) for delivering an aerosolized compound (e.g. nicotine at col.5, line 58), the device comprising: a reservoir (10) that stores the compound; a system comprising an entry port (12) and an element (14) to generate particles of a desired size for physical ejection through one or more apertures (15) from an ejection head (14) of the element, wherein said particles comprise a compound (e.g. nicotine at col.5, line 58), and wherein said system is fluidly connected (11) to a reservoir (10); and a housing (2,3) comprising an inlet (7) and an outlet (5) between which is formed an airflow path (see bold arrows in fig.2 extending from outside of housing 2,3 through inlet 7 and through outlet 5) and in which at least the ejection head is disposed in the air flow path (i.e. as illustrated in fig.2) downstream of the inlet (7) and upstream from the outlet (5), wherein the housing provides for a substantially unobstructed airflow between the ejection head and the outlet when air traverses the airflow path from the inlet to the outlet.

As to claims 2 and 3, in Voges the compound (col.5, line 58) is a pharmaceutical compound and is stored in the reservoir (10) in a liquid formulation (col.5, line 58 discloses nicotine dissolved in water).

As to claims 4-7, Voges (col.9, line 53-col.10, line 21) discloses a variety of suitable drugs for delivery by the device. These drugs include proteins and hormones (e.g. corticosteroids and antidiuretic hormone), and small molecules (e.g. budesonide) as well as other drugs which are fully capable of being gene delivery vehicles.

As to claim 8, the reservoir (10) and particle generating system (14,15) in Voges (fig.2) are illustrated as being located within housing (2,3).

As to claim 9, the housing of Voges (fig.2) is aerodynamically shaped (e.g. cylindrically shaped thereby providing for easy flow of air therethrough and around).

As to claim 10, the reservoir (10) of Voges is disclosed as being detachable (col.6, lines 37-40).

As to claim 11, the reservoir (10) and particle generating system (11,12,14,15) of Voges is illustrated (e.g. in fig.2) as being integrated into a single unit.

As to claim 12, the particle generating system of Voges is an electronic ejection device (col.6, lines 45-51).

As to claim 13, Voges discloses the electronic ejection device uses heat (20 and col.6, lines 26-30) to generate particles ejected from the ejection head.

As to claim 14, Voges discloses the electronic ejection device includes a piezoelectric component (col.10, lines 52-54) to generate particles ejected from the ejection head.

As to claims 15-17, Voges discloses the desired particle size is one which allows particles to transit to and be deposited in alveoli (col.9, lines 37-47). That is, Voges recognizes that particles having a diameter less than 5 microns are preferred because particles of this size range will follow respiratory passages. One of ordinary skill would recognize respiratory passages to include alveoli.

As to claim 18, fig.2 of Voges illustrates substantially unobstructed airflow being substantially laminar prior to exiting the housing outlet (5).

As to claim 19, fig.2 of Voges illustrates substantially unobstructed airflow comprises a substantially homogeneous mixture of ejected compound and air from inlet (7) prior to exiting the housing outlet (5).

Claims 21-24 are substantially equivalent in scope to claims 1 and 18 and are anticipated by Voges for the reasons set forth above with respect to claims 1 and 18.

Claims 25-42 are substantially equivalent in scope to claims 1-19 and are anticipated by Voges for the reasons set forth above with respect to claims 1-19. Voges as discussed above also discloses a digitally controlled electronic ejection (col.6, lines 45-51) of aerosolized medicament.

The balance of the claims, 43-61,63-84, are substantially equivalent in scope to claims 1-19,21-42 and are anticipated by Voges for the reasons set forth above with respect to claims 1-19,21-42.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 20 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voges ('841) in view of Gonzalez ('614).

The difference between Voges and claim 20 is an inner surface of the housing is proximal to the ejection head and extending to the outlet is contoured to minimize turbulence.

Gonzalez, in a device for delivering an aerosolized compound (page 1, col.2, lines 100+), teaches an inner surface of the housing is proximal to the aerosol generation system and extending to the outlet is contoured (A' to a2 to e2 of fig.1). The contouring of the inner surface of the housing of Gonzalez would implicitly cause variations in the flow rate and flow pattern of the aerosol being formed as it passes therethrough (e.g. smaller diameter portions would cause increased flow rate and more laminar flow whereas increased diameter portions would cause decreased flow rate and relatively more turbulent flow.

It would have been obvious to modify the inner surface of the housing proximal to the ejection head to make it contoured because it would have provided a means for controlling the flow rate and flow pattern of the aerosol being formed as taught by Gonzalez.

Claim 62 is substantially equivalent in scope to claim 20 and is included in Voges as modified by Gonzalez for the reasons set forth above with respect to claim 20.

***Response to Arguments***

5. Applicant's arguments filed 07/20/2005 have been fully considered but they are not persuasive. Applicant's assertion that Voges lacks a "substantially unobstructed airflow between the ejection head and the outlet is not accurate because Voges (fig.2) clearly illustrates a space between ejection head (14) and outlet (5) having only a single element (heater 20) therein and this heater is illustrated as permitting airflow therethrough as indicated by airflow arrows; moreover, Voges (col.6, lines 23-24) discloses that heater (20) is optional thus eliminating any structural element between ejection head (14) and outlet (5).

Applicant's arguments that Gonzalez lacks a substantially unobstructed airflow is noted; however, it is Voges that discloses a substantially unobstructed airflow as discussed above. The propriety of the combination of Voges and Gonzalez is valid for the reasons set forth above in the body of the rejection of claim 20.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
AARON J. LEWIS  
Primary Examiner  
Art Unit 3743

Aaron J. Lewis  
October 03, 2005